REMARKS

Claim Amendments

Independent claim 39 has been amended to recite, "An oligonucleotide probe comprising a sequence of at least 12 contiguous nucleotides of a human mitochondrial genome...." The specification supports this amendment by teaching, "The probe can optionally contain at least 12, 14, 16, 18, 20, 22, 24, 26, or 30 such contiguous nucleotides." Specification at page 3, lines 8-10.

Independent claim 40 has been amended to recite, "An oligonucleotide primer comprising a sequence of at least 12 contiguous nucleotides of a human mitochondrial genome...." The specification supports this amendment by teaching, "The primer can optionally contain at least 12, 14, 16, 18, 20, 22, 24, 26, or 30 such contiguous nucleotides." Specification at page 4, lines 3-4.

Claims 39 and 40 have also been amended to recite an oligonucleotide comprising "a ΔC mutation at nucleotide 303." This amendment corrects an inadvertent nucleotide numbering error. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction. *In re* Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).

The specification originally but erroneously disclosed "ΔC mutation at nucleotide 302." Specification at page 3, line 12 and at page 4, lines 6-7. The nucleotide at position 302 of SEQ ID NO:1 however is not a "C" and therefore cannot be mutated to delete a "C". The specification should have recited a "ΔC mutation at nucleotide 303."

As pointed out by the Examiner, "the nucleotide at position 302 of SEQ ID NO:1 is an 'A.' That 'A' is followed by a run of 7 'C' bases at positions 303-309." Office Action at page 2, lines 17-18. One skilled in the art would immediately realize that a ΔC mutation cannot occur at position 302 because an "A" is present, not a "C." One skilled in the art would also recognize that the ΔC mutation would occur within the run of 7 "C" bases which begins immediately after nucleotide 302, *i.e.,* at nucleotide 303. Thus, one skilled in the art would not only have recognized this error, but also the appropriate

correction. Applicants have corrected this mistake by amending the specification to read, "ΔC mutation at nucleotide 303."

The U.S. Patent and Trademark Office already assumed this correction when conducting a search for the invention. The Office Action states that "[f]or purposes of prior art, the claims will be interpreted as meaning one of two different possibilities. Either SEQ ID NO:1 already has the deletion of the 'C' base or there is a deletion of a 'C' subsequent to position 302, resulting in a run of 6 'C' bases in the place of the seven 'C' bases shown in SEQ ID NO:1." Office Action at page 2, line 21 – page 3, line 2 (emphasis added). Since SEQ ID NO:1 is the wild-type sequence, as indicated in the specification (page 8, lines 18-20) the latter possibility is the correct one. As stated in the Office Action, the Examiner has already conducted a search for prior art containing a ΔC mutation at nucleotide 303.

Claims 118 and 126 are cancelled.

Specification Amendments

The specification has been amended to remove the embedded hyperlinks within the paragraphs beginning on page 8 at line 18, page 12 at line 4, page 12 at line 16, and page 19 at line 4.

The specification has also been amended to correct an inadvertent nucleotide numbering error. Table 2 and pages 3, 4, and 5 of the specification initially referred to a ΔC mutation at nucleotide 302. As discussed above, the specification should have disclosed a ΔC mutation at the nucleotide subsequent to nucleotide 302, *i.e.*, nucleotide 303, and one skilled in the art would clearly have recognized the correct position.

Rejection of Claims under 35 U.S.C. §112

Claims 39, 40, and 118-126 stand rejected under 35 U.S.C. §112, second paragraph, for being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse the rejection.

The Office Action asserts that the claims are indefinite because "the term ΔC mutation at nucleotide 302 is indefinite in the context of the sequence submitted as SEQ ID NO:1." Office Action at page 2, lines 14-15. Claims 39 and 40 have been amended to recite an oligonucleotide primer or probe wherein the oligonucleotide comprises a "ΔC mutation at nucleotide 303." Thus, claims 39 and 40 and dependent claims 118-126 are definite, as amended.

Applicants respectfully request withdrawal of the rejection.

Rejection of Claims under 35 U.S.C. §102(b) -- Genbank Accession No. V00662

Claims 39, 40, and 118-126 stand rejected under 35 U.S.C. §102(b) as being anticipated by Genbank Accession No. V00662. Applicants traverse the rejection.

To reject a claim as anticipated, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Claims 39 and 40 as amended recite an oligonucleotide primer or probe wherein the oligonucleotide comprises a "ΔC mutation at nucleotide 303."

The Office Action states that "[t]his rejection relies upon the interpretation that SEQ ID NO:1 already has the deletion of the "C" base." Office Action at page 3, lines 12-13. However, this interpretation is incorrect. The specification discloses that, "[m]itochondrial mutations are determined with reference to wild-type human mitochondrial sequence. Sequence information can be found at the website gen.emory.edu/mitomap.html and at SEQ ID NO:1." Specification at page 8, lines 18-20. Thus, SEQ ID NO:1 is the wild-type sequence. The rejection assumes that SEQ ID NO:1 already contains the ΔC mutation, *i.e.,* is a mutant sequence. Because SEQ ID NO:1 does not contain the ΔC mutation, Genbank Accession No. V00662 does not teach each and every element set forth in the claim and therefore does not anticipate the claimed oligonucleotides.

Rejection of Claims under 35 U.S.C. §102(b) -- Genbank Accession No. U25391

Claims 39, 40, and 118-126 stand rejected under 35 U.S.C. §102(b) as being anticipated by Genbank Accession No. U25391. Applicants traverse the rejection.

To reject a claim as anticipated, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

Genbank Accession No. U25391 is a 715 base pair DNA sequence. The Office Action asserts that "Genbank Accession NO. U25391 teaches a sequence which has a deletion of a C relative to SEQ ID NO:1 after position 302, and comprises 52 contiguous nucleotides identical to the delta 302 C deletion of SEQ ID NO:1." Office Action at page 4, lines 10-12.

Claim 39 recites an "oligonucleotide probe" and claim 40 recites an "oligonucleotide primer." An "oligonucleotide probe," as defined by Strachan and Read's Human Molecular Genetics 2, is a short single-stranded piece of DNA, "typically 15-50 nucleotides." See Exhibit 1, page 1, line 16. Chou *et al.* teaches, "25-30mer probes are short oligonucleotide probes and 50-80mer probes are long oligonucleotide probes." See Exhibit 2, page 1, right hand column, lines 13-15. An "oligonucleotide primer" is defined by Strachan and Read as "about 15-25 nucleotides long." See Exhibit 3, page 1, line 15. In Brown's Genomes 2 textbook, Brown defines an oligonucleotide primer as "a short DNA oligonucleotide, typically 20 nucleotides in length...." See Exhibit 4, page 2, line 3. Genbank Accession No. U25391 is not an oligonucleotide. At 715 base pairs, it is approximately 35 times larger than what those of skill in art consider an oligonucleotide. Thus, Genbank Accession No. U25391 fails to teach each and every element as set forth in claims 39, 40, and 118-126 and therefore does not anticipate the claimed invention.

Rejection of Claims under 35 U.S.C. §102(b) -- Brennen *et al.*

Claims 39 and 40 stand rejected under 35 U.S.C. §102(b) as being anticipated by Brennen *et al.* (U.S. Patent 5,474,796). Applicants traverse the rejection.

To reject a claim as anticipated, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

The Office Action asserts that "Brennan teaches the formation of an array which comprises every single 10-mer." Office Action at page 5, line 3. Claims 39 and 40 have been amended to recite an oligonucleotide probe or primer "comprising a sequence of at least 12 contiguous nucleotides...." Brennen does not teach probes of at least 12 nucleotides. Therefore, Brennen does not anticipate the claimed invention.

Applicant respectfully requests withdrawal of the rejection.

Respectfully submitted,

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By: _____
Sarah A. Kagan
Registration No. 32,141

Banner & Witcoff, Ltd.
Customer No. 22907

Enclosures

Exhibit 1: Strachan, T. and Read, A. Human Molecular Genetics 2. Chapter 5.1. 1999. Online Textbook.
Exhibit 2: Chou *et al.* Nucleic Acids Research, Vol. 32 No. 12. e99. 2004.
Exhibit 3: Strachan, T. and Read, A. Human Molecular Genetics 2. Chapter 5.1. 1999. Online Textbook.
Exhibit 4 : Brown, T.A. Genomes 2. Chapter 2. Section 5.3. 2002. Online Textbook